accordance with the requirements of 37 C.F.R. § 1.121, a marked up version of the claims showing the changes, is attached as Appendix A.

REMARKS

Status of the Claims.

Claims 1-47 are pending in the application. Claim 22 has been amended. Support for these amendments is found throughout the specification and in original claim 25. Therefore, the amendments do not add new matter.

Election/Restriction.

In the Office Action, the Examiner restricted the claims under 35 U.S.C. § 121, requiring Applicants to elect one of the following claim groups for prosecution in the present application:

> Group I, claim(s) 1-4, 6-14, 22-24, 26-35 and 39, drawn to a pharmaceutical composition that provide an elastin-based composition comprising [a] polypeptide or peptide of elastins, tropoelastins, or a fragment there of and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle function by delivering said elastin-based composition.
>
> Group II, claim(s) 5 and 25, drawn to a pharmaceutical composition that provides an elastin-based composition comprising an expression vector encoding a tropoelastin or a fragment thereof, and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle function by delivering said elastin-based composition.
>
> Group III, claim(s) 15-21, drawn to a method of producing an elastin-based composition by treating a blood vessel . . . and a method for preparing a biocompatible support comprising an elastin-based composition.
>
> Group IV, claim(s) 1, 22 and 36-38, drawn to a pharmaceutical composition that provides an elastin-based composition comprising one or more elastic fiber[s], and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle function by delivering said elastin-based composition, wherein said pharmaceutical composition is a tubular elastin based composition [such] as an artificial blood vessel.

> Group V, claim(s) 40-42, drawn to a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle function . . . by administering an elastase inhibitor to an individual.
>
> Group VI, claim(s) 43 and 44, drawn to a method to screen for a drug candidate . . . comprising administering a drug to an ELN+/- or ELN-/- organism or cell and [determining] . . . the increase of elastin mRNA . . . .
>
> Group VII, claim(s) 43 and 45, drawn to a method to screen for a drug candidate . . . comprising administering a drug to an ELN+/- or ELN-/- organism or cell and [determining] . . . the increase of elastin protein level . . . .
>
> Group VIII, claim(s) 43 and 46, drawn to a method to screen for a drug candidate . . . comprising administering a drug to an ELN+/- or ELN-/- organism or cell and [determining] . . . the increase of elastin activity . . . .
>
> Group IX, claim(s) 43 and 47, drawn to a method to screen for a drug candidate . . . comprising administering a drug to an ELN-/- organism or cell and measuring inhibition of vascular smooth muscle cell (VSMC) proliferation, stimulation of VSMC differentiation, or regulation VSMC migration.

Office Action, pages 3-4. The Examiner indicated that claims 1 and 22 link Claim Groups I and IV and that Claim 43 links Claim Groups VI-IX. Office Action, page 4. The restriction requirement is respectfully traversed.

First, the Examiner states that inventions I, II, IV, and V are not related because, allegedly:

> Ranju et al., 1987 (The Journal of Biological Chemistry, Vol. 262, p. 5755-5762) discloses the cDNA sequence encoding bovine elastin (e.g. p. 5757) and Fazio et al, 1988 (Laboratory Investigation, Vol. 58, p. 270-277) discloses the cDNA sequence encoding human elastin and elastin gene expression in cultured skin fibroblasts (e.g. title, p. 272). Thus, no special technical feature that contributes over the prior art has been provided.

Office Action, page 5. This statement suggests that the Examiner views the "special technical feature" as, simply, elastin cDNA. Applicants respectfully submit that this view fails to take into account all of the elements of the pending claims and cannot therefore serve as justification for

restricting among Claim Groups I, II, IV, and V. The Examiner points out differences among the subject matter of the remaining claim groups and concludes that, because of these differences, "inventions I-IX do not relate to a single general inventive concept under PCT Rule 13.1." Office Action, page 6. That this analysis is flawed is clear when one considers, for example, that claim 43 is a generic claim that appears in Claim Groups VI-IX. The other claims in these claim groups depend from claim 43. Thus, claim 43 clearly embodies a general inventive concept that, at a minimum, unites Claim Groups VI-IX. Applicants therefore submit that simply pointing out differences among the subject matter of the various claim groups is insufficient to justify the restriction requirement.

Second, Applicants submit that Claim Group II should include claims 1 and 22. More specifically, Claim Group II includes claims 5 and 25, which are composition and method claims, respectively. Claim 5 depends from claim 1, which recites a "pharmaceutical composition that provides an elastin-based composition to a target site in vivo." Claim 5 relates to an embodiment of the invention wherein the pharmaceutical composition comprises an expression vector. Thus, claim 1 is generic to claim 5. Claims 22 and 25 are similarly related. That is, claim 25 depends from claim 22, which recites "delivery of the elastin-based composition provided by the pharmaceutical composition of claim 1 to the target site." Claim 22 has been amended to ensure that this claim is understood to encompass the embodiment of the invention in which the elastin-based composition is provided by an expression vector. Claim 25 relates to the embodiment wherein the pharmaceutical composition comprises an expression vector Thus, claim 22 is generic to claim 25. (Applicants note that the amendment to claim 22 does not change the scope of this claim, but rather substitutes language that is more appropriate in view of the dependency of claim 25 from claim 22.)

Applicants note that the Examiner apparently recognized that claims 1 and 22 were generic with respect to claims classified in Claim Groups I and IV and properly identified claims 1 and 22 as linking claims for these groups. Because claims 1 and 22 are also generic with respect to claims classified in Claim Group II, Applicants submit that claims 1 and 22, in fact, link Claim Groups I, II, and IV. Applicants respectfully request modification of the restriction requirement to reflect this point.

Third, Applicants submit that claims 36-38 are generic with respect to claims classified in Claim Groups I and IV and should therefore appear in both claim groups and, further, be identified as linking claims. In particular, claim 36 depends from claim 35, which itself depends

from method claim 22. Method claim 22 is generic with respect to the type of elastin-based composition employed. Claim 35 requires that the elastin-based composition be "delivered to and maintained at said [target] site." Claim 36 further requires that the elastin-based composition be a "tubular elastin-based composition." None of these three claims restrict the type of the elastin-based composition employed, which can include one or more of "elastic fibers, elastins, tropoelastins, or fragments thereof," as recited in claim 1. Claims 37 and 38 depend from claim 36 and recite different uses of the composition, but also do not restrict the type of elastin-based composition employed. Thus, claims 36-38 are, like claims 1 and 22, generic with respect to the elastin-based composition.

In an Examiner Interview, the Examiner indicated that he had believed that the recitation of a "tubular elastin-based composition" in claim 36 restricted the claim to the use of elastin fibers. However, as Applicants' Attorney pointed out, the specification uses the word "tubular" to refer to the shape of the elastin-based composition, not its make-up. For example, the specification states:

> [E]lastin-based composition can be molded to a suitable size and shape for specific applications. . . .
>
> * * *
>
> Elastin-based compositions can . . . be molded into tubular segments, for example, by injection of solutions or suspensions of the compositions into tubular molds. . . . Tubular segments of such elastin-based compositions can be used in the treatment of vascular disease, as discussed above for elastin tubes prepared from blood vessels.

Applicants' specification, page 27, line 29 – page 28, line 13. Of course, as one skilled in art readily appreciates, the term "tubular elastin-based composition" includes an elastin matrix produced from a blood vessel, as disclosed in Applicants' specification at page 22, line 23 through page 25, line 9 (which describes the matrix as a "tubular elastin matrix" at page 25, line 1).

As claims 36-38 read on methods employing any of the elastin-based compositions recited in claim 1, claims 36-38 should be included in Claim Group I, relating to polypeptides or peptides of elastins, tropoelastins, or fragments thereof, as well as Claim Group IV, relating to elastic fibers. Furthermore, like generic claims 1 and 22, generic claims 36-38 should be identified as linking claims that link Claim Groups I and IV. Modification of the restriction requirement to reflect this point is respectfully requested.

In summary, Applicants request withdrawal of the restriction requirement on the ground that the Examiner has not cited adequate justification for the requirement. If the restriction requirement is maintained, Applicants request modification of Claim Groups I, II, and IV as follows:

Group I: Claims 1-4, 6-14, 22-24, and 26-39

Group II: Claims 1, 5, 22, and 25

Group IV Claims 1, 22, 36-38.

Applicants further request that claims 1 and 22 be identified as linking claims for Claim Groups I, II, and IV and that claims 36-38 be identified as linking claims for Claim Groups I and IV.

Applicants provisionally elect Claim Group I with traverse. According to current Patent Office practice, a restriction requirement that divides species encompassed by linking claims should be provisional, subject to the non-allowance of the linking claims. If, however, the linking claims are found to be allowable, Applicants are entitled to have claims to the species encompassed by the linking claims examined in one application.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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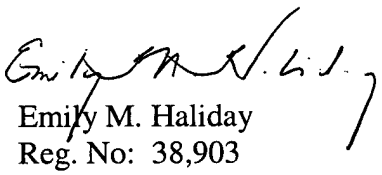
Respectfully submitted,



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APPENDIX A

"MARKED UP" CLAIMS ILLUSTRATING THE AMENDMENTS MADE TO THE CLAIMS OF 09/554996 WITH ENTRY OF THIS AMENDMENT

22. A method for prophylaxis or treatment of a disorder characterized by diminished capacity to regulate smooth muscle cell function comprising delivery of the elastin-based composition provided by [in] the pharmaceutical composition of claim 1 to said target site.